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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/661,231	Applicant(s) RAMSTAD ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18-21 and 24-27 is/are rejected.
- 7) ☒ Claim(s) 16, 17, 22 and 23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/07/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 11, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (US 6,375,817 B1).

Addressing claim 1, Taylor discloses a channel device comprising

a substrate (25) comprising a plurality of channels (12) for electrophoresis separation (col. 5:55-66 and col. 7:18-23); and

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a plurality of deflectable cilia ((28) – that capillaries 28 are deflectable is shown in Figures 6 and 7) in fluid communication with the plurality of channels (Figure 6; col. 9:66 – col. 10:9; col. 10:60 – col. 11:8; and col. 14:18-28), wherein the deflectable cilia are adapted to loading the plurality of channels from a multi-well tray (Although a multi-well tray is not mentioned in Taylor, the cilia are adapted as claimed because they are closely spaced apart in a row at a regular interval and are curved at the sample injection end from a horizontal position to a vertical position so that sample can be obtained by dipping the sample injection ends of the cilia into an array of liquid spots containing the sample . See Figures 6 and 7 and col. 13:65 – col. 14:17).

Addressing claims 2 and 3, for the additional limitation of this claim note temperature control device 42 in Figure 6, which supports the outlet ends of the cilia and deflects them downwards. For claim 3 note that the temperature control device 42 is “active” since it adjusts temperature as desired by heating or cooling. See col. 12:35-61.

Addressing claim 4, for the additional limitation of this claim see col. 6:4-22.

Addressing claim 11, Taylor discloses a loading mechanism for a channel device comprising

a plurality of deflectable cilia ((28) – that capillaries 28 are deflectable is shown in Figures 6 and 7) to fluidly communicate with the plurality of channels (Figure 6; col. 9:66 – col. 10:9; col. 10:60 – col. 11:8; and col. 14:18-28) in a substrate (25) for electrophoretic separation (col. 5:55-66 and col. 7:18-23), wherein the deflectable cilia are adapted to loading the plurality of channels from a multi-well tray (Although a multi-well tray is not mentioned in Taylor, the cilia are adapted as claimed because they are closely spaced apart in a row at a regular interval and are curved at the sample injection end from a horizontal position to a vertical position so that sample can be obtained by dipping the sample injection ends of the cilia into an array of liquid spots containing the sample . See Figures 6 and 7 and col. 13:65 – col. 14:17); and

a support adapted to deflect the cilia to load the channels from the multi-well tray (note temperature control device 42 in Figure 6, which supports the outlet ends of the cilia and deflects them downwards).

Addressing claim 18, Liu also implicitly discloses an active mechanism to control the cilia deflection because "... the present invention comprises accessories for automated matrix filling, chip injector cleanup, sample loading and sequencing separation ... the entire system is automated to allow rapid throughput with minimal human intervention." See col. 3:63 – col. 4:3.

Addressing claim 19, for the additional limitation of this claim the Examiner broadly construes deflection as a type of deformation.

3. Claims 1, 2, 4-6, 11-15, and 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu (US 6,533,914 B1).

Addressing claim 1, Liu discloses a channel device comprising
a substrate (separation chip – Figure 11) comprising a plurality of channels (unlabeled, but shown in Figure 11) for electrophoresis separation (abstract and col. 7:15-19); and

a plurality of deflectable cilia (connection capillaries – Figure 11) in fluid communication with the plurality of channels (Figure 11), wherein the deflectable cilia are adapted to loading the plurality of channels from a multi-well tray (sample preparation chip – Figures 1 and 11). Note that the connection capillaries of Liu are inherently deflectable because Applicant states, “Cilia can be, for example, capillary tubes.” See paragraph [017] in the specification.

Addressing claim 2, for the additional limitation of this claim see col. 14:14-21 and Figure 6 (note molded plastic injector).

Addressing claim 4, for the additional limitation of this claim see col. 4:55-60.

Addressing claims 5 and 20, Liu discloses a system for electrophoretic separation (abstract and col. 7:15-19) comprising

a channel device comprising a substrate (separation chip – Figure 11) comprising a plurality of channels and a plurality of deflectable cilia (connection capillaries – Figure 11) in fluid communication with the plurality of channels (Figure 11);

a multi-well tray (sample preparation chip – Figures 1 and 11); and
a support adapted to deflect the cilia to load the channels from the multi-well array. See col. 14:14-21 and Figure 6 (note molded plastic injector).

Note that the connection capillaries of Liu are inherently deflectable because Applicant states, “Cilia can be, for example, capillary tubes.” See paragraph [017] in the specification.

Addressing claim 6, a controller as claimed is implied by Liu because “... the present invention comprises accessories for automated matrix filling, chip injector cleanup, sample loading and sequencing separation ... the entire system is automated to allow rapid throughput with minimal human intervention.” See col. 3:63 – col. 4:3.

Addressing claims 11, 20 and 21, Liu discloses a loading mechanism for a channel device comprising

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a plurality of deflectable cilia (connection capillaries – Figure 11) to fluidly communicate with the plurality of channels (Figure 11) in a substrate (separation chip – Figure 11) for electrophoretic separation (abstract and col. 7:15-19), wherein the deflectable cilia are adapted to loading the plurality of channels from a multi-well tray (Figure 11 and col. 3:20-53); and

a support adapted to deflect the cilia to load the channels from the multi-well tray (See col. 14:14-21 and Figure 6 (note molded plastic injector)).

As for the method steps of claims 20 and 21 these are just using the channel device of described above as intended and are shown or implied by Figures 1, 6, and 11. For example, Figure 11 shows a multi-well tray (sample preparation chip) that has been provided and at least one deflected cilium from a plurality of cilia adapted to fluidly communicate with a plurality of channels in the channel device (separation chip). Figure 6 shows detail of the support (molded plastic injector) used for deflecting at least one cilium:

Addressing claim 12, for the additional limitation of this claim note that the molded plastic injector that fits only the inlet end of a cilium can be construed as a “post.” See col. 14:14-21 and Figure 6 (note molded plastic injector).

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Addressing claims 13-15, for the additional limitations of these claims see Figures 1 and 11.

Addressing claim 19, for the additional limitation of this claim the Examiner broadly construes deflection as a type of deformation.

4. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Foret et al. (US 6,939,452 B2) ("Foret").

Addressing claim 1, Foret discloses a channel device comprising
a substrate (12) comprising a plurality of channels (20) for electrophoresis separation (abstract and col. 2:25-27); and
a plurality of deflectable cilia (11) in fluid communication with the plurality of channels (Figure 1), wherein the deflectable cilia are adapted to loading the plurality of channels from a multi-well tray (Figure 11; col. 1:55 – col. 2:7; col. 2:35-41; col. 5:4-9; and col. 4:65 – col. 5:3). Note that the connection capillaries of Foret are inherently deflectable because Applicant states, "Cilia can be, for example, capillary tubes." See paragraph [017] in the specification.

Addressing claim 4, for the additional limitation of this claim see col. 2:27-31.

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5. Claims 1, 2, 4, 10, 11, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathies et al. (US 2002/0006359 A1) ("Mathies").

Addressing claim 1, Mathies discloses a channel device comprising
a substrate (111) comprising a plurality of channels (not shown, but implied because the substrate is for capillary array electrophoresis. See paragraphs [0003] and [0039]) for electrophoresis separation (implied because the substrate is for capillary array electrophoresis. See paragraphs [0003] and [0039]); and

a plurality of deflectable cilia (107) in fluid communication with the plurality of channels (Figure 1), wherein the deflectable cilia are adapted to loading the plurality of channels from a multi-well tray (Figure 1 and abstract). Note that the connection capillaries of Mathies are inherently deflectable because Applicant states, "Cilia can be, for example, capillary tubes." See paragraph [017] in the specification. Furthermore, Figure 1 shows both ends of the cilia being deflected.

Addressing claim 2, for the additional limitation of this claim see paragraph [0043].

Addressing claim 4, for the additional limitation of this claim see paragraph [0048] (note the scanner).

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Addressing claim 5, Mathies discloses a system for electrophoretic separation (implied because the substrate is for capillary array electrophoresis. See paragraphs [0003] and [0039]) comprising

a channel device comprising a substrate (111) comprising a plurality of channels (not shown, but implied because the substrate is for capillary array electrophoresis. See paragraphs [0003] and [0039]) and a plurality of deflectable cilia (107) in fluid communication with the plurality of channels (Figure 1);

a multi-well tray (Figure 1 and abstract); and

a support (109) adapted to defect the cilia to load the channels from the multi-well support (Figure 1 and paragraph [0043]).

Addressing claim 10, for the additional limitation of this claim see Figure 3 and paragraph [0049].

Addressing claims 11, 20, and 21, Mathies discloses a loading mechanism for a channel device comprising

a plurality of deflectable cilia (107) to fluidly communicate with the plurality of channels (not shown, but implied because the substrate is for capillary array electrophoresis. See paragraphs [0003] and [0039].) in a substrate (111) for electrophoretic separation (paragraphs [0003] and [0039]), wherein the deflectable cilia are adapted to loading the plurality of channels from a multi-well tray (abstract); and

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a support (109) adapted to deflect the cilia to load the channels from the multi-well tray (Figure 1 and paragraph [0043]).

As for the method steps of claims 20 and 21 these are just using the channel device of described above as intended and are shown or implied by Figure 1. For example, Figure 1 shows a multi-well tray (105) that has been provided and at least one deflected cilium from a plurality of cilia adapted to fluidly communicate with a plurality of channels in the channel device (11). Figure 1 also shows without detail support (109) used for deflecting at least one cilium.

Addressing claim 19, for the additional limitation of this claim the Examiner broadly construes deflection as a type of deformation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (US 6,533,914 B1).

Addressing claim 7, Liu discloses a system for electrophoretic separation (abstract and col. 7:15-19) comprising

a channel device comprising a substrate (separation chip – Figure 11) comprising a plurality of channels and a plurality of deflectable cilia (connection capillaries – Figure 11) in fluid communication with the plurality of channels (Figure 11);

a multi-well tray (sample preparation chip – Figures 1 and 11); and
a support adapted to deflect the cilia to load the channels from the multi-well array. See col. 14:14-21 and Figure 6 (note molded plastic injector).

Note that the connection capillaries of Liu are inherently deflectable because Applicant states, “Cilia can be, for example, capillary tubes.” See paragraph.[017] in the specification.

Liu also implicitly discloses a controller as claimed because “... the present invention comprises accessories for automated matrix filling, chip injector cleanup, sample loading and sequencing separation ... the entire system is automated to allow rapid throughput with minimal human intervention.” See col. 3:63 – col. 4:3.

Liu does not mention having a CPU adapted to direct the controller; however, it would have been obvious to one with ordinary skill in the art at the time of the invention

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to do so because a CPU (or computer) was used at the time of the invention for robotic analytical workstations, such as the Biomek 1000, which is mentioned by Liu (col. 11:34-42 and abstract of "Utilization of a computer-controlled laboratory workstation (Biomek 1000) in routine radioimmunoassay laboratory," Issac Hassan, Comput. Biol. Med. 1990;20(3):185-191) and because a CPU will allow a set of complex instructions to be programmed into the automated system.

Addressing claim 8, for the additional limitation of this claim see col. 4:55-60.

Addressing claim 9, Liu does not mention having the detector be in electrical communication with the CPU as claimed; however, it would have been obvious to one with ordinary skill in the art to do so because, for example, it is important to know at least which sample was loaded into a particular separation channel so that the detection results can be associated with the correct sample.

10. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al. (US 2002/0006359 A1) ("Mathies") in view of Balch et al. (US 6,479,301 B1) ("Balch").

Mathies discloses a method for electrophoretic separation comprising

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providing a channel device comprising a substrate (111) comprising a plurality of channels (not shown, but implied because the substrate is for capillary array electrophoresis. See paragraphs [0003] and [0039]) and a plurality of deflectable cilia (107) in fluid communication with the plurality of channels (Figure 1);

providing a multi-well tray (105);

deflecting at least one cilium to load at least one sample from the multi-well tray (implied by Figure 1, which shows the inlet ends of the cilia placed into the samples wells of the multi-well tray);

deflecting the plurality of cilia into a buffer tray (implied by Figure 3, which shows the inlet ends of the cilia next inserted into buffer tray 103 (paragraph [0049]; and

providing electric current for the electrophoresis separation (this is obvious because it is necessary to perform electrophoresis separation).

Mathies does not mention providing a loading mechanism to defect the cilia to load the channels from the multi-well tray.

Balch discloses a loading mechanism (robotic arm) to deflect an array of regularly spaced cilia into a multi-well tray. See Figures 4, 4a, and 4b. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a loading mechanism as taught by Balch in the invention of Mathies because it much more convenient, accurate, and faster to use an automated loading mechanism as taught by Balch than to have a technician defect the cilia by hand.

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Addressing claims 25 and 26, these additional steps are implied by Figure 1 of Mathies, which shows the cilia positioned for loading samples from the multi-well tray to the channel device.

Addressing claim 27, it should be first noted that Mathies discloses a detector. See paragraph [0048] (note the scanner). It would have been obvious to one with ordinary skill in the art at the time of the invention to detect electrophoresis separation information from a detection zone on the channel device because then the sample constituents can be identified and/or quantitated.

Claim Objections

11. Claims 12 and 22 are objected to because of the following informality:

- a) Claim 12: in line 2 "of" should be deleted; and
- b) Claim 22, line 3: "connect" should be -- connected.--

Appropriate correction is required.

Allowable Subject Matter

12. Claims 16, 17, 22, and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 16 requires the cilia to comprise a shape-memory alloy adapted to provide resilience to return the cilia to an initial position after the defection. In Taylor the cilia are glass or plastic capillaries. See col. 9:25-33. In Liu the cilia are capillaries, which one with ordinary skill in the art would understand to be silica or glass capillaries. See Figure 11 and col. 13:63 – col. 14:5. In Mathies the cilia are fused silica or plastic or stainless steel capillaries. See paragraphs [0039], [0041], or [0042].

b) Claim 17 requires the cilia to comprise a tendon element to control the deflection. In Taylor the cilia are deflected by the housing of the temperature

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control device 42. See Figure 6. In Liu the cilia are deflected by molded plastic injectors into which the inlet ends are placed. See Figures 6 and 1 and col. 14:14-21. in Mathies the cilia are deflected by a manifold with throughholes for the cilia. See paragraph [0043].

c) Claim 22 requires the step of "positioning at least one of the channel devices and the multi-well tray to align the cilia to posts connect to the support." In Liu the "posts" (molded plastic injector shown in Figure 6; col. 14:14-21) is the support.

d) Claim 23 depends from allowable claim 22.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner
AU 1753
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